

Food and Drug Administration**21 CFR Part 510****Animal Drugs, Feeds, and Related Products; Change of Sponsor Address**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Bioproducts, Inc.

EFFECTIVE DATE: February 7, 1995.

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1737.

SUPPLEMENTARY INFORMATION: Bioproducts, Inc., has informed FDA of a change of address from 8221 Brecksville Rd., Cleveland, OH 44141, to 320 Springside Dr., suite 300, Fairlawn, OH 44333-2435. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the new address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for "Bioproducts, Inc.," and in the table in paragraph (c)(2) in the entry for "051359" by removing "8221 Brecksville Rd., Cleveland, OH 44141" and adding in its place "320 Springside Dr., suite 300, Fairlawn, OH 44333-2435".

Dated: January 31, 1995.

George A. Mitchell,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 95-2992 Filed 2-6-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 558**New Animal Drugs for Use in Animal Feeds; Tylosin**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Premiere Agri Technologies, Inc., providing for making a 20-gram-per-pound (g/lb) tylosin Type A medicated article in addition to existing approvals for 40- and 100-g/lb Type A medicated articles.

EFFECTIVE DATE: February 7, 1995

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1700.

SUPPLEMENTARY INFORMATION: Premiere Agri Technologies, Inc. (Premiere), P.O. Box 2508, Fort Wayne, IN 46801-2508, filed a supplement to NADA 91-582 (formerly sponsored by Central Soya Co., Inc.) that provides for making a new 20-g/lb tylosin Type A medicated article used to make Type C medicated feeds for cattle, chickens, and swine for use as in § 558.625(f)(1)(i) through (f)(1)(vi) (21 CFR 558.625(f)(1)(i) through (f)(1)(vi)). Premiere currently has approval for 40- and 100-g/lb Type A medicated articles. The supplemental NADA is approved and the regulations are amended in § 558.625(b)(10) to reflect the approval. Approval of this supplemental NADA is an administrative action that did not require the generation of new safety or effectiveness data. Therefore, a freedom of information summary is not required for this action.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds. Therefore, under the Federal Food, Drug, and Cosmetic Act and under the

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.625 is amended by revising paragraph (b)(10) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(10) To 012286: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

* * * * *

Dated: January 11, 1995.

Andrew J. Beaulieu,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95-2990 Filed 2-6-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 117**

[CGD02-94-016]

RIN 2115-AE47

Drawbridge Operation Regulation; Red River, AR

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is separating the regulations governing drawbridges on the Red River into two sections, one for Louisiana and one for Arkansas. Currently, the entire length of the Red River in both Arkansas and Louisiana is regulated in one CFR Section. The completion of U.S. Army Corps of Engineer projects at locks and dams 4 and 5 in December 1994 is expected to result in an increase of commercial traffic on the Red River in Louisiana, necessitating a change in drawbridge openings only for the portion of the river flowing in Louisiana. This amendment allows the drawbridge on the Red River in Louisiana and Arkansas to be regulated under separate CFR sections but makes no substantive changes to the regulations for

drawbridges over the Red River in Arkansas.

EFFECTIVE DATE: This rule is effective on February 7, 1995.

FOR FURTHER INFORMATION CONTACT:

Roger K. Wiebusch, Bridge Administrator, Second Coast Guard District, (314) 539-3724.

SUPPLEMENTARY INFORMATION: This rulemaking is procedural in that it changes the location in the CFR of existing regulations, but does not substantively change the requirements of these regulations. Therefore, under the provisions of 5 U.S.C. 553(b)(3), notice and an opportunity to comment is not required and this rule may be made effective upon publication.

Drafting Information

The principal persons involved in drafting this document are Roger K. Wiebusch, Project Officer, Bridge Branch, and LT S. Moody, Project Attorney, Second Coast Guard District Legal Office.

Discussion of Change

The Red River flows through both the states of Louisiana and Arkansas. The drawbridges over the Red River in both states have been regulated in one CFR section, § 117.35, which was cross referenced in § 117.491. This rule, together with a separate rule revising § 117.491 (CGD08-94-026), concerning the drawbridges over the Red River in Louisiana separates the regulation of the drawbridges over the Red River by state.

As a result of the completion of locks and dams 4 and 5 in December 1994 by the U.S. Army Corps of Engineers, the Red River will open for commercial navigation in late January 1995. The completion of these projects is expected to cause an increase in the commercial vessel traffic on the Louisiana section of the Red River. No changes in traffic are anticipated on the Arkansas portion. However, the anticipated increase in vessel traffic on the Louisiana portion of the Red River has necessitated a change in drawbridge openings over the Red River in Louisiana. The changes for bridges over the Red River in Louisiana are published elsewhere in today's issue of the **Federal Register**, docket number CGD08-94-26. Section 117.491 now regulates only the drawbridges over the Red River in Louisiana. The rule revises § 117.135 to now regulate only those drawbridges over the Red River in Arkansas. This final rule makes no substantive changes to the operating requirements of the Arkansas drawbridges.

Regulatory Evaluation

This rule is not significant regulatory action under 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

The Coast Guard finds that the impact on small entities, if any, is not substantial. Therefore, the Coast Guard certifies under 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Environment

The Coast Guard has reviewed the environmental impact of this rule and concluded that under section 2.B.2 of the NEPA Implementing Procedures, COMDTINST M16475.1B, this proposal is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the human environment. A Categorical Exclusion Determination is available in the docket for inspection or copying in the docket.

List of Subjects in 33 CFR Part 117

Bridges.

PART 117—DRAWBRIDGE OPERATION REGULATIONS

For the reasons set out in the preamble, the Coast Guard proposes to amend Part 117 of Title 33, Code of Federal Regulations, as follows:

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. Section 117.135 is revised to read as follows:

§ 117.125 Red River.

The draws of the bridges above Mile 276.0 at the Arkansas Louisiana border, need not be open for the passage of vessels.

Dated: January 23, 1995.

Paul M. Blayney,
Rear Admiral, U.S. Coast Guard, Commander,
Second Coast Guard District.

[FR Doc. 95-2995 Filed 2-6-95; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 117

[CGD08-94-026]

RIN 2115-AE47

Drawbridge Operation Regulation; Red River, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: With the completion of locks and dams 4 and 5 in December 1994 by the U.S. Army Corps of Engineers, the Red River will be open for commercial navigation in late January 1995. At present, all bridges up to mile 177.9 must open on signal with at least 48-hours advance notice. The continuation of such a rule would severely restrict the movement of prospective commercial navigation on the waterway and would create a burden on the bridge owners. This final rule changes the regulation governing the operation of six drawbridges across the Red River located between mile 59.5 and mile 105.8. Bridges located between mile 105.8 and mile 234.4 will remain on 48-hours advance notice. Bridges located above mile 234.4 need not be opened for the passage of vessels. This rule will accommodate the needs of vehicular traffic and still provide for the reasonable needs of navigation.

EFFECTIVE DATE: February 7, 1995.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Commander(ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana 70130-3396, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589-2965.

FOR FURTHER INFORMATION CONTACT: Mr. John Wachter, Bridge Administration